

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

JESSICA L. TEAL,

Plaintiff,

Case No. 20-cv-11018

v.

UNITED STATES DISTRICT COURT
JUDGE GERSHWIN A. DRAIN

ARGON MEDICAL DEVICES, INC.,
ET AL.,

Defendants.

**OPINION AND ORDER GRANTING DEFENDANT ARGON’S MOTION
TO DISMISS [#38] AND GRANTING IN PART AND DENYING IN PART
DEFENDANT REX’S MOTION TO DISMISS [#37]**

I. INTRODUCTION

Plaintiff Jessica Teal (“Plaintiff”) filed the instant products liability lawsuit against Defendants Argon Medical Devices, Inc., Rex Medical, Inc., d/b/a Rex Medical, L.P., and Rex Medical, L.P (together, “Defendants”). ECF No. 1. Plaintiff seeks to recover damages for injuries she allegedly sustained following the surgical implantation for the Option Filter System medical device in February 2014. On December 23, 2020, Plaintiff filed her Third Amended Complaint. ECF No. 34.

Presently before the Court is Defendant Rex Medical, Inc. d/b/a Rex Medical, L.P. and Rex Medical, L.P.’s (collectively, “Rex”) Motion to Dismiss, filed on

January 6, 2021. ECF No. 37. Defendant Argon Medical Devices, Inc.’s (“Argon”) Motion to Dismiss, also filed on January 6, 2021, is before the Court as well. ECF No. 38. Defendants’ separate motions are fully briefed. A hearing on these motions was held on April 7, 2021. For the reasons that follow, the Court will **GRANT** Argon’s Motion to Dismiss [#38]. Additionally, the Court will **GRANT IN PART** and **DENY IN PART** Rex’s Motion to Dismiss [#37].

II. BACKGROUND

Plaintiff brings this diversity action against Defendants after a surgically implanted medical device, the Option Inferior Vena Cava Filter (hereinafter, “Option Filter”) failed and allegedly caused multiple struts to perforate her inferior vena cava (“IVC”). According to Rex, the Option Filter is designed to be implanted in the IVC and intended to prevent recurrent and potentially fatal pulmonary embolism. ECF No. 37, PageID.544. Plaintiff claims that she suffered “serious, life threatening injuries” as a result of the Option Filter. ECF No. 34, PageID.485. A

On or about February 7, 2014, Plaintiff underwent surgery for the implantation of the Option Filter at St. Joseph Mercy in Ypsilanti, Michigan. *Id.* at PageID.191. Plaintiff later underwent an IVC filter retrieval attempt at Michigan Medicine University of Michigan Hospital on or about August 23, 2017, where the surgeon was able to retrieve the Option Filter and all but one fractured strut. *Id.* The remaining strut was determined to be outside of Plaintiff’s IVC. *Id.* According to

Plaintiff, she has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses as a result of Defendants' medical device. ECF No. 24, PageID.352.

Rex obtained the Food and Drug Administration's ("FDA") clearance to market the Option Filter and its components in June 2009 through the 510(k) process. ECF No. 34, PageID.486. Plaintiff avers that "Argon, as the exclusive sales agent for the Option Filters, and the Rex Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Option filter[.]" *Id.* at PageID.489. Specifically, Plaintiff alleges that Rex "designed, manufactured, advertised, distributed, sold and/or supplied" the Option Filter, while Argon "marketed, advertised, distributed, sold, and/or supplied" the Option Filter. *Id.* She claims that the Option Filter was marketed despite it being unsafe and defective "due to the inadequate warnings, instructions, labeling, and/or inadequate testing[.]" *Id.* According to Plaintiff, Rex represented that the Option Filter was substantially equivalent to several other vena cava filters. ECF No. 41, PageID.725. The Option Filter which she received, however, was purportedly "unable to withstand normal anatomical and physiological loading cycles exerted *in vivo*, and subject to an inappropriate degree of risk of tilting, embedment, breakage, migration, perforation, and fracture." *Id.* at PageID.725–26.

On December 3, 2020, the Court denied without prejudice Defendants' separate Motions to Dismiss (ECF Nos. 18 and 22). ECF No. 31. In its Opinion and Order, the Court concluded that the interests of judicial economy were best served if Plaintiff was afforded an opportunity to amend her complaint and provide Defendants "fair notice" of the grounds upon which her claims can rest. *Id.* at PageID.433. The Court thus ordered Plaintiff to file an amended complaint no later than December 11, 2020.¹ *Id.* at PageID.435. The parties appeared before the Court for a Status Conference on January 6, 2021. ECF No. 35. Defendants separately filed their renewed Motions to Dismiss, which are presently before the Court, that same day. ECF Nos. 37, 38.

In her Third Amended Complaint, Plaintiff alleges the following claims against Defendants: (1) negligence (Count I); (2) breach of implied warranty of merchantability and fitness for a particular purpose (Count II); (3) breach of express warranty (Count III); and (4) negligent misrepresentation (Count IV).² ECF No. 34.

¹ The parties submitted a Stipulation/Consent Order on December 22, 2020 that Plaintiff would file a Third Amended Complaint by December 23, 2020 and that Defendants' responsive pleadings would be filed by January 6, 2021. ECF No. 33.

² Plaintiff also includes a non-numbered section titled "MCLA § 600.2949(a) Knowledge of Defective Product. ECF No. 34, PageID.522. In her Response briefs, Plaintiff asserts that she included this section in order to "place the Defendants on notice that she intends to argue [this statutory safeguard] and offer evidence on it at trial." *See* ECF No. 40, PageID.714.

Rex and Argon now separately move to dismiss Plaintiff's Third Amended Complaint through their respective motions. ECF Nos. 37, 38.

III. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) allows the court to make an assessment as to whether the plaintiff has stated a claim upon which relief may be granted. *See* Fed. R. Civ. P. 12(b)(6). To withstand a motion to dismiss pursuant to Rule 12(b)(6), a complaint must comply with the pleading requirements of Federal Rule of Civil Procedure 8(a)(2). *See Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009). Rule 8(a)(2) requires “a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quotation marks omitted) (quoting Fed. R. Civ. P. 8(a)(2); *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). To meet this standard, a complaint must contain sufficient factual matter, accepted as true, to “state a claim to relief that is plausible on its face.” *Twombly*, 550 U.S. at 570; *see also Iqbal*, 556 U.S. at 678–80 (applying the plausibility standard articulated in *Twombly*).

When considering a Rule 12(b)(6) motion to dismiss, the Court must construe the complaint in a light most favorable to the plaintiff and accept all of his factual allegations as true. *Lambert v. Hartman*, 517 F.3d 433, 439 (6th Cir. 2008). While courts are required to accept the factual allegations in a complaint as true, *Twombly*,

550 U.S. at 556, the presumption of truth does not apply to a claimant's legal conclusions. *See Iqbal*, 556 U.S. at 678. Therefore, to survive a motion to dismiss, the plaintiff's pleading for relief must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Ass'n of Cleveland Fire Fighters v. City of Cleveland*, 502 F.3d 545, 548 (6th Cir. 2007) (quoting *Twombly*, 550 U.S. at 555) (internal citations and quotations omitted).

IV. ANALYSIS

A. Argon's Motion to Dismiss (ECF No. 38)

In its present Motion, Argon moves for dismissal of all counts. ECF No. 38. Argon emphasizes that it's a "non-manufacturing seller." *Id.* at PageID.628. Plaintiff did not dispute Argon's status at the hearing. Indeed, in her Third Amended Complaint, Plaintiff asserts that Rex, not Argon, obtained FDA clearance to market the Option Filter and designed and manufactured the Option Filter. ECF No. 34, PageID.486, 490.

As a non-manufacturing seller of the Option Filter at issue in this case, Argon asserts that its liability is limited to product liability theories pursuant to Mich. Comp. Laws § 600.2947(6). ECF No. 38, PageID.628. In that section, any claims against a non-manufacturing seller are limited to (a) those alleging the failure to exercise reasonable care, including breach of an implied warranty, and (b) those

alleging the breach of an express warranty. Mich. Comp. Laws § 600.2947(6); *Curry v. Meijer, Inc.*, 780 N.W.2d 603, 610 (Mich. Ct. App. 2009).

1. Negligence (Count I) and Breach of Implied Warranty (Count II)

“Traditional principles of products liability law recognize three types of defects: manufacturing defects, defects due to faulty design, and defects due to inadequate instructions or warnings.” *Fleck v. Titan Tire Corp.*, 177 F. Supp. 2d 605, 613 (E.D. Mich. 2011) (citation omitted). In Michigan, “negligence” and “implied warranty” are two theories of recovery which are recognized in product liability cases. *Auto Club Grp. Ins. Co. v. All-Glass Aquarium Co., Inc.*, 716 F. Supp. 2d 686, 689 (E.D. Mich. 2010) (citation omitted). A breach of implied warranty claim tests the “fitness of the product,” while a negligence claim tests a defendant’s conduct to determine “whether it was reasonable under the circumstances.” *Id.* (citations omitted).

Regardless of whether a plaintiff is proceeding under a negligence theory or a breach of implied warranty theory, she must, at minimum, establish: “(1) that the product was defective; (2) that the product was defective when it left the control of the defendant; and (3) that the defective product caused the plaintiff’s injuries.” *Meemic Ins. Co. v. Hewlett-Packard Co.*, 717 F. Supp. 2d 752, 768 (E.D. Mich. 2010) (citing *Kupkowski v. Avis Ford, Inc.*, 235 N.W.2d 324, 328 (Mich. 1975)). In Count I of her Third Amended Complaint (negligence), Plaintiff avers that Argon,

as the exclusive sales agent for the Option Filter, knew or should have known that the Option Filter was, among other purported risks, “designed and manufactured in a way as to present an unreasonable risk of tilt and or embedment ...; an unreasonable risk perforation ...; an unreasonable risk of migration” ECF No. 34, PageID.510–11. In Count II (breach of implied warranty), Plaintiff alleges that the Option Filter was “not in a merchantable condition” and that Argon “impliedly represented and warranted ... that the Option filter was safe and of merchantable quality.” *Id.* at PageID.515.

In its present briefs, Argon argues that Plaintiff fails to plead the requisite independent negligence in either Counts I or II pursuant to Mich. Comp. Laws § 600.2947(6). As indicated *supra*, Michigan law limits a non-manufacturing seller’s liability to instances where the seller failed to exercise reasonable care, including breach of any implied warranty, and where there is a breach of an express warranty.³ See *Baye v. HBI Branded Apparel Enters.*, No 12-cv-12869, 2013 WL 6546815, at *4 (E.D. Mich. Dec. 13, 2013) (citing Mich. Comp. Laws § 600.2947(6)). The Sixth Circuit has explained that the plain language of § 600.2947(6)(a) “indicates that the legislature did not intend failure to exercise reasonable care and breach of implied warranty to be separate product liability

³ The Court will address Plaintiff’s claim for a breach of an express warranty (Count III) against Argon in the next section.

claims” for non-manufacturing sellers. *Croskey v. BMW of N. Am., Inc.*, 532 F.3d 511, 520 (6th Cir. 2008). “[T]he only claim envisioned by the legislature in § 600.2947(6)(a) was failure to exercise reasonable care.” *Id.* The Court will thus analyze Counts I and II against Argon, a non-manufacturing seller, together pursuant to § 600.2947(6)(a).

Upon careful review of the Third Amended Complaint, the Court finds that Plaintiff does not plausibly allege that Argon, as a non-manufacturing seller, “failed to exercise reasonable care” with respect to the Option Filter. While Plaintiff’s allegations may be enough to state a claim for a defective product, they are not enough to establish a failure to exercise reasonable care claim under § 600.2947(6)(a). Indeed, the Court is unable to locate any allegations of independent negligence on Argon’s part in order to establish a failure to exercise reasonable care claim. At this juncture, “[t]o demonstrate that a defendant failed to exercise reasonable care, the court must evaluate whether the plaintiff demonstrated that the defendant knew or should have known of the defect.” *Bishop v. Enerco Grp., Inc.*, No. 16-11770, 2016 WL 5905991, at *2 (E.D. Mich. Oct. 11, 2016) (citing *Kraft v. Dr. Leonard’s Healthcare Corp.*, 646 F. Supp. 2d 882, 888 (6th Cir. 2009)) (internal quotation marks omitted). Plaintiff’s conclusory allegations that Argon “knew and should have known that the device was defective and unreasonably dangerous”—set forth in ¶ 47, ECF No. 34, PageID.491; *see also* ECF

No. 40, PageID.707–08—do not transform otherwise insufficient factual pleadings into allegations that plausibly support an inference of independent negligence on Argon’s part as required for a non-manufacturing seller defendant.

The Court “must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (citation omitted). Plaintiff’s allegations as to Argon’s conduct as a non-manufacturing seller are insufficient for her claims to survive dismissal. Accordingly, the Court will dismiss Plaintiff’s negligence and implied warranty claims, alleged as separate Counts I and II, against Argon.

2. Breach of Express Warranty (Count III)

Plaintiff alleges in Count III that Argon breached express warranties under Michigan Uniform Commercial Code, Mich. Comp. Laws § 400.2313.⁴ ECF No. 34, PageID.517. Plaintiff avers that Argon:

expressly represented and warranted that the Option filter was safe and used sales aids, among other things, comparing the lack of complaints in the FDA’s MAUDE database for its filter as compared to that of other

⁴ Michigan recognizes a breach of express warranty claim as a product liability theory in addition to one brought pursuant to the UCC. Plaintiff does not address the product liability theory/UCC distinction in her Response to Argon’s present Motion. Notably, she does not allege in her Third Amended Complaint that she and Argon were parties to an agreement with one another. The Court will evaluate her breach of express warranty claim against Argon under a product liability theory, rather than one based in the UCC, which, as discussed *infra* in relation to Rex, includes a privity requirement under Michigan law.

IVC filter manufacturers, while knowing that the lack of data in the MAUDE database was inherently flawed and an unreliable source of information to demonstrate the safety of the Option Filter.

ECF No. 34, PageID.517. She claims that Argon made this representation “at the specific instruction of the Rex Defendants.” *Id.* Moreover, Plaintiff asserts that she, “through her attending physicians, relied on these representations in determining which IVC filter to use ... and the misrepresentations by Argon were beyond mere puffery.” *Id.* at PageID.518.

As discussed above and set forth in Mich. Comp. Laws § 600.2947(6)(b), a plaintiff can bring a breach of express warranty claim against a non-manufacturing seller. The parties agree that a breach of express warranty claim under Michigan law requires: (1) proof of an express warranty, (2) reliance by the plaintiff; (3) the failure of the product to meet the warranty, and (4) damages caused by the failure. ECF No. 38, PageID.641; ECF No. 40, PageID.716. Upon review of the Third Amended Complaint, the Court agrees with Argon that Plaintiff’s express warranty claim is devoid of any facts as to “when, how, and by whom an express warranty that the product was ‘safe’ was made.” ECF No. 38, PageID.642. Moreover, the claim does not specify the terms of the alleged express warranty. *Id.* Rather, Plaintiff avers that “[a]t the time and place of advertising, marketing, sale, distribution, and supply of the Option filter to Plaintiff, Argon ... expressly

represented and warranted that the Option filter was safe and effective” ECF No. 34, PageID.517.

At the hearing, Plaintiff directed the Court to ¶¶ 35 and 75 of her Third Amended Complaint to rebut Argon’s argument that her claim is devoid of factual allegations. In these paragraphs, Plaintiff avers that Argon “widely advertised and promoted [the Option Filter] as a safe and effective permanent placement” and “represented that the self-centering design of the Option filter and Option Elite filter allows accurate, predictable placement, and that its struts reduce the risk of tilting and migration” ECF No. 34 PageID.488, 498. The Court finds that these allegations, similar to the ones discussed above, are conclusory and devoid of the requisite specificity for the claim to proceed.

In sum, while Plaintiff is correct to denote that she “need only plead factual allegations sufficient to reasonably ‘inform the adverse party of the nature of the claim[,]’ ECF No. 40, PageID.717 (citation omitted), the Court finds that her express warranty claim is devoid of such requisite factual allegations. Plaintiff’s generalities to support the existence of an express warranty are insufficient for this claim against Argon to survive dismissal.

Accordingly, the Court will dismiss Plaintiff’s express warranty claim (Count III) against Argon.

3. Negligent Misrepresentation (Count IV)

In Count IV of her Third Amended Complaint, Plaintiff avers that Argon, “at the specific instruction of the Rex Defendants,” knowingly made false and negligent misrepresentations and omissions about the Option Filter. ECF No. 34, PageID.519–22. She alleges that Argon made misrepresentations related to the Option Filter’s safety, efficacy, rate of failure, and its approved uses. *Id.* at PageID.519. According to Plaintiff, the information distributed by Argon was in the form of “reports, press releases, advertising campaigns, labeling materials, print advertisements, [and] commercial media[.]” *Id.*

Under Michigan law, a negligent misrepresentation claim requires a plaintiff to prove that a defendant made a material misrepresentation, which was false, and amounted to a breach of a business or professional duty of care to provide accurate information to her. *See Lackowski v. Twinlab Corp.*, No. 00-75058, 2001 U.S. Dist. LEXIS 25634, at *29–30 (E.D. Mich. Dec. 28, 2001). Moreover, a plaintiff must prove that she suffered damages as a result. *Id.* In its present Motion, Argon asserts that Plaintiff’s negligent misrepresentation claim is not sufficiently pleaded as required by Federal Rule of Civil Procedure 9(b). ECF No. 38, PageID.643. This rule provides that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed .R. Civ. P. 9(b). To satisfy this standard, the Third Amended Complaint must “(1) specify the statements the plaintiff contends were fraudulent; (2) identify the speaker; (3) state where and when

the statements were made; and (4) explain why the statements were fraudulent.” *La. Sch. Employees' Ret. Sys. v. Ernst & Young, LLP*, 662 F.3d 471, 478 (6th Cir.2010). At minimum, a plaintiff “must allege the time, place and contents of the misrepresentations upon which [she] relied.” *Frank v. Dana Corp.*, 547 F.3d 564, 569–70 (6th Cir. 2008). “The threshold test is whether the complaint places the defendant on sufficient notice of the misrepresentation, allowing the defendant[] to answer, addressing in an informed way the [plaintiff's] claim of fraud.” *Kashat v. Paramount Bancorp, Inc.*, No. 09-10863, 2010 WL 538295, at *4 (E.D. Mich. Feb. 10, 2010) (citation omitted).

Argon contends that Plaintiff’s negligent misrepresentation claim is “devoid of any identification or description of a representation that [it] actually made.” ECF No. 43, PageID.773. Upon review of Plaintiff’s Third Amended Complaint, the Court agrees. Plaintiff’s general allegations fail to put Argon on notice of any specific statements that were fraudulent, nor do they explain why such statements were fraudulent. Moreover, the Court finds that Plaintiff fails to indicate where and when any alleged misrepresentations were made. As another district court within the Sixth Circuit has explained, a negligent misrepresentation claim “requires more than the mere promotion or sale of a defective product; it requires specific misrepresentations of fact, which Plaintiff[has] not identified with any specificity.”

Tice v. Zimmer Holdings, Inc., No. 1:15-cv-134, 2015 WL 4392985, at *8 (W.D. Mich. July 15, 2015).

In making this determination, the Court finds Plaintiff's argument that she need not plead her negligent misrepresentation claim with particularity as required by Rule 9(b) unavailing. *See* ECF No. 40, PageID.718. Indeed, another court within this District has held that a negligent misrepresentation claim, as with fraud, "requires proof that the defendant misrepresented a past or existing fact." *Miller v. Laidlaw & Co. (UK) Ltd.*, No. 11-12086, 2013 WL 1278484, at *2 (E.D. Mich. Mar. 27, 2013) (citations omitted) (finding a palpable error by not considering a plaintiff's negligent misrepresentation claims under heightened scrutiny). In *Miller*, the district court relied on the Sixth Circuit and the Eastern District of Michigan's precedent that such a claim must meet a heightened pleading standard set forth in Rule 9(b). *Id.* at *1 (citing *Smith v. Bank of Am. Corp.*, 485 F. App'x 749, 752–53 (6th Cir. 2012); *Qadeer v. Bank of Am., N.A.*, 2013 WL 424776 (E.D. Mich. Feb. 4, 2013)). Upon review of Plaintiff's brief, ECF No. 40, PageID.718, it is clear that her cited authority—*Santander Consumer USA, Inc. v. Superior Pontiac Buick GMC, Inc.*, No. 10-13181, 2011 U.S. Dist. LEXIS 33068, at *14–15 (E.D. Mich. Mar. 29, 2011) and *Hanover Exch. V. Metro Equity Grp. LLC*, No. 08-14897, 2009 U.S. Dist. LEXIS 59992, at *27–28 (E.D. Mich. July 14, 2009)—predates this Court's binding

precedent as set forth in *Miller*. Accordingly, the Court finds that Plaintiff fails to meet her burden under the heightened scrutiny pursuant to Rule 9(b).

Moreover, the Court finds that Plaintiff's negligent misrepresentation claim must also fail in light of Argon's status as a non-manufacturing seller. As indicated *supra*, Plaintiff's claims against Argon, a non-manufacturing seller, are limited to (a) those alleging the failure to exercise reasonable care, including breach of any implied warranty, and (b) those alleging the breach of an express warranty. Mich. Comp. Laws § 600.2947(6). Plaintiff avers that any representations were made "at the specific instruction of the Rex Defendants," *see, e.g.*, ECF No. 34, PageID.520, yet fails to offer any factual allegations related to how the alleged material was false or incomplete, or how Argon could have known the information was false or incomplete such that it was negligent in distributing it. In sum, Plaintiff's claim does not include the requisite factual allegations to establish how Argon, as a non-manufacturing seller, failed to exercise reasonable care in disseminating the alleged misrepresentations.

Accordingly, Plaintiff's negligent misrepresentation claim (Count IV) must also be dismissed.

4. Plaintiff's Corporate/Vicarious Liability Allegations

Argon also disputes Plaintiff's corporate/vicarious liability allegations. ECF No. 38, PageID.646. In her Third Amended Complaint, Plaintiff avers that:

the Argon and Rex Defendants were agents, servants, partners, aiders and abettors, co-conspirators and/or joint venturers, with regard to the marketing, sale and distribution of the Option Filter and Option Elite Filter, including the filter implanted in the Plaintiff, and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to each other, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

ECF No. 34, PageID.507. Moreover, Plaintiff alleges that a “unity of interest” exists between Defendants “with regard to the marketing, sale and distribution of the Option Filter and Option Elite Filter. *Id.* at PageID.507–08. According to Plaintiff, Argon and Rex are “individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff’s damages.” *Id.* at PageID.508.

Argon contends that Plaintiff’s corporate/vicarious liability allegations “should not be permitted as a catchall to impute all conduct of one Defendant to the other.” ECF No. 38, PageID.646. While Plaintiff did not address Argon’s argument in her Response, she stated at the hearing that “an agency relationship” exists between Defendants. Upon careful review of her Third Amended Complaint, the Court disagrees with Plaintiff and finds that the corporate/vicarious liability allegations do not revive her aforementioned claims against Argon. Plaintiff does not offer factual allegations that would allow the Court to infer that an agency relationship exists between Argon and Rex. Rather, Plaintiff’s Third Amended Complaint includes vague and indeterminate assertions that a joint interest existed

between Argon and Rex. Such indeterminate allegations are “the type of naked conspiratorial allegations rejected by the Supreme Court in *Twombly*.” *Tam Travel, Inc. v. Delta Airlines, Inc.*, 583 F.3d 896 (6th Cir. 2009) (citation omitted).

Accordingly, the Court concludes that Plaintiff’s corporate/vicarious liability allegations cannot revive her four separate claims against Argon.

5. Plaintiff’s Request for Additional Leave

As a final matter, the Court takes notice of Plaintiff’s repeated request for leave to amend her Third Amended Complaint should any deficiencies remain. *See, e.g.*, ECF No. 40, PageID.714. The Court declines to afford Plaintiff another opportunity to amend at this juncture after it denied without prejudice Argon’s and Rex’s original Motions to Dismiss, and thus provided Plaintiff another opportunity to correct the deficiencies in her Complaint. *See* ECF No. 31, PageID.432. The Court emphasizes that Plaintiff amended her Complaint twice after the Court’s ruling. *See* ECF Nos. 32, 34.

In sum, the Court will grant Argon’s Motion to Dismiss in its entirety. Plaintiff’s claims against Argon are therefore dismissed with prejudice.

B. Rex’s Motion to Dismiss (ECF No. 37)

In its separate Motion, Rex moves for dismissal of Plaintiff’s Third Amended Complaint for insufficient specificity and for failure to state a claim upon which

relief can be granted. ECF No. 37. The Court will address each of Plaintiff's four counts as to Rex in its analysis below.

1. Judicial Notice

As a preliminary matter, Rex requests that the Court take judicial notice of several FDA documents: (1) FDA website publication on Pre-market Notification/510(k) Clearance Process; (2) Guidance for Cardiovascular Intravascular Filter 510(k) Submissions; and (3) FDA Guidelines on Investigational Device Exemptions, including 21 C.F.R. 812.25. ECF No. 37, PageID.547–48. Rex contends that where Plaintiff's Third Amended Complaint relies on representations regarding steps taken to conform with publicly available FDA guidance documentation and regulations, the Court should take notice of these documents. *Id.* at PageID.548. Plaintiff objects to this request, arguing that the applicability of any FDA guidance is subject to interpretation. ECF No. 41, PageID.726. She asserts that "issues regarding the relevance, admissibility, and legal effect of [these] documents will be in dispute in this litigation." *Id.*

Federal Rule of Evidence 201 provides that a court may take judicial notice of an adjudicative fact "that is not subject to reasonable dispute" because it "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). In ruling on a motion to dismiss, a court may therefore "consider materials in addition to the complaint if such materials are public

records or are otherwise appropriate for the taking of judicial notice.” *New England Health Care Employees Pension Fund v. Ernst & Young, LLP*, 336 F.3d 495, 501 (6th Cir. 2003). Both the Pre-market Notification/510(k) Clearance Process and Guidance for Cardiovascular Intravascular Filter 510(k) Submissions are publicly available federal agency documents related to the FDA’s premarket approval procedure—which Plaintiff discusses in her Third Amended Complaint—and the Court thus grants Rex’s request in part. *See Hill v. Bayer Corp.*, 485 F. Supp. 3d 843, 848 (E.D. Mich. Sept. 8, 2020) (taking judicial notice of publicly available FDA document related to a device’s premarket approval); *Albrecht v. Fort Dodge Animal Health Inc.*, No. 12-11429, 2013 U.S. Dist. LEXIS 30449, at *9 n.2 (E.D. Mich. Mar. 6, 2013). Accordingly, the Court takes judicial notice thereof to the limited extent that these publications, available on the FDA’s website, provide additional background on the 510(k) clearance process. The Court declines to exercise its discretion in taking judicial notice of the FDA Guidelines on Investigational Device Exemptions in light of Plaintiff’s assertion that the Option Filter at issue in this matter was not an investigational device. ECF No. 41, PageID.727.

1. Negligence (Count I)

In Count I, Plaintiff brings a general negligence claim against Rex, who “designed, manufactured, marketed, advertised, inspected, labeled, promoted, distributed and sold” the Option Filter. ECF No. 34, PageID.509. She alleges that

Rex “had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, advertising, labeling, promotion, distribution and sale” of the Option Filter. *Id.* According to Plaintiff, Rex breached its duty of reasonable care and was negligent for reasons set forth in ¶ 124, including in “[u]nreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Option Filter ...” and “[r]epresenting that the Option Filter was safe for its intended use” *Id.* at PageID.511–12.

To reiterate, in order to prevail in a products negligence action, a plaintiff must show that: (1) the product was defectively manufactured; (2) the product reached the plaintiff in the same condition that it was in when it left the manufacturer; and (3) the defect proximately caused the plaintiff's injury. *See Meemic Ins. Co. v. Hewlett-Packard Co.*, 717 F. Supp. 2d 752, 768 (E.D. Mich. 2010); *Prentis v. Yale Mfg.*, 365 N.W.2d 176, 186 (Mich. 1985). A plaintiff is not required to point to a specific defect, but she must provide more than “mere supposition” to establish that there was a defect. *Meemic Ins. Co.*, 717 F. Supp. 2d at 771.

In its present Motion, Rex first argues that two subparts of Plaintiff's negligence claim—subparts (f) and (l)—fail as a matter of law and should be dismissed. ECF No. 37, PageID.553. These subparts read as follows:

The Rex Defendants breached their duty of reasonable care and were negligent in:

...

f. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

...

l. Continuing manufacture and sale of the Option Filter with the knowledge that said product was dangerous and not reasonably safe and failing to comply with the F.D.A. good manufacturing regulations.

ECF No. 34, PageID.511–12. Rex challenges the legal sufficiency of these subparts, arguing that they are each deficient to establish a manufacturing defect claim. *Id.* at PageID.554–55.

Plaintiff contests Rex’s argument that she has not presented sufficient factual support to establish a negligent manufacturing claim. ECF No. 41, PageID.732. She emphasizes in her Response that the allegations in subparts (f) and (l) are examples of Rex’s alleged negligent conduct, rather than independent legal conclusions. ECF No. 41, PageID.732–33. Upon review of these subparts, the Court agrees with Plaintiff that Rex’s argument challenges two of Plaintiff’s factual allegations as if they are a separate cause of action for negligent manufacturing. Indeed, Plaintiff has pleaded a general negligence claim against Rex, rather than solely a design defect claim. She alleges that Rex had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of the Option Filter as to avoid exposing others to foreseeable and unreasonable risks of harm. In ¶ 124, she purports that Rex breached

this duty in several ways, including that it failed to use reasonable care in producing a product that differed from Rex's design or specifications or from other typical units (subpart (f)) and that it continued to manufacture and sell the Option Filter with the knowledge that the product was dangerous and unsafe (subpart (l)). She purports that Rex's devices suffer from a design defect that causes them to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo. According to Plaintiff, she suffered, and will continue to suffer, serious injuries as a direct and proximate result of Rex's negligence.

At this stage of the proceedings, the Court must accept the factual allegations presented in Plaintiff's Third Amended Complaint as true. *Lambert v. Hartman*, 517 F.3d 433, 439 (6th Cir. 2008). Upon review of Plaintiff's factual allegations as to Rex in Count I, the Court concludes that Plaintiff has stated a plausible claim in order to proceed with her negligence action. *See Meemic Ins. Co.*, 717 F. Supp. 2d at 768. Accordingly, the Court will deny Rex's Motion on the grounds that subparts (f) and (l) are legally insufficient to establish a manufacturing defect claim.

Rex also argues that Plaintiff's failure to warn allegations, some of which are included in Count I, must fail as a matter of law in light of the sophisticated user doctrine. Under Michigan law, to establish that a product is defective due to failure to warn, a plaintiff must demonstrate that the defendant: "(1) had actual or constructive knowledge of the alleged danger, (2) had no reason to believe that

consumers would know of this danger, and (3) failed to exercise reasonable care to inform consumers of the danger.” *Hollister v. Dayton Hudson Corp.*, 201 F.3d 731, 741 (6th Cir. 2000). Here, Plaintiff avers that Rex had actual or constructive knowledge that the Option Filter could not withstand the normal anatomical and physiological loading cycles exerted in vivo. In Count I, Plaintiff specifically alleges that Rex failed to use “reasonable care to warn or instruct, including pre- and post-sale, Plaintiff, Plaintiff’s physicians, or the general health community about the Option Filter’s substantially dangerous condition or about facts making the product likely to be dangerous.” ECF No. 34, PageID.511.

Rex invokes the sophisticated user doctrine to argue that Plaintiff’s failure to warn claim must fail. ECF No. 37, PageID.562. This doctrine provides that “a manufacturer or seller is not liable in a product liability action for failure to provide an adequate warning if the product is provided for use by a sophisticated user.” Mich. Comp. Laws § 600.2947(4). A “sophisticated user” is expressly defined as:

a person or entity that, by virtue of training, experience, a profession, or legal obligations, is or is generally expected to be knowledgeable about a product's properties, including a potential hazard or adverse effect. An employee who does not have actual knowledge of the product's potential hazard or adverse effect that caused the injury is not a sophisticated user.

Mich. Comp. Laws § 600.2945(j). Under this doctrine, defendants can assume that sophisticated users “have a mastery of the basic operation” of a product. *Brown v.*

Drake-Willock Int'l, Ltd., 530 N.W.2d 510, 516 (Mich. Ct. App. 1995). The Michigan Court of Appeals has explained that “where a purchaser is a ‘sophisticated user’ of a manufacturer's product, the purchaser is in the best position to warn the ultimate user of the dangers associated with the product, thereby relieving the sellers and manufacturers from the duty to warn the ultimate user.” *Portelli v. I.R. Constr. Prods. Co.*, 554 N.W.2d 591, 599 (Mich. Ct. App. 1996). Rex asserts that Option Filters are prescription devices that are sold directly to health care providers and are not available to the general public. ECF No. 37, PageID.563. It thus argues that the sophisticated user doctrine controls, and it “only had a duty to warn the health care facility where the surgery occurred and/or Plaintiff’s trained and credentialed implanting physician, Dr. Borlaza[.]” *Id.* Rex further contends that it satisfied that duty to the health care facility and/or Dr. Borlaza. *Id.*

The Court denotes, however, that the question of whether a user knew or should have known about a product’s dangerous characteristics depends on the circumstances of a particular case, including the knowledge and experience of the user and the nature of the risks. *See Heaton v. Benton Constr. Co.*, 780 N.W.2d 618, 623 (Mich. Ct. App. 2009) (determining that a general contractor was not a sophisticated user of the product at issue). At this early stage of the case, the Court is unable to discern whether “by virtue of training, experience, a profession, or legal obligations” a physician like Dr. Borlaza could be “generally expected to be”

knowledgeable about the risks associated with the Option Filter and the complications experienced by Plaintiff. The Court thus declines to rule in Rex's favor based on the sophisticated user doctrine at this juncture without such information. Other district courts within the Sixth Circuit have recently declined to apply the sophisticated user doctrine before discovery has commenced. *See Tice v. Zimmer Holdings, Inc.*, No. 15-cv-134, 2015 WL 4392985, at *7 (W.D. Mich. July 15, 2015) (denying defendants' motion to dismiss to the extent that it relied on the sophisticated user doctrine); *see also McClarty v. C.R. Bard Inc.*, No. 14-cv-13627, 2020 WL 6075520, at *10–11 (E.D. Mich. Oct. 15, 2020) (discussing the doctrine's applicability post-discovery in resolving defendant's motion for summary judgment stage). The Court will revisit this issue post-discovery should it be raised in a later dispositive motion.⁵ Accordingly, the Court will deny Rex's Motion to the extent that it relies on this doctrine.

In sum, the Court will deny Rex's Motion as it relates to Plaintiff's negligence claim (Count I).

2. Breach of Implied Warranty (Count II)

⁵ The Court will also determine whether Mich. Comp. Laws § 600.2949(a), which Plaintiff includes at the conclusion of her Third Amended Complaint, ECF No. 34, PageID.522, is relevant should Rex later raise the doctrine's applicability post-discovery.

In Count II, Plaintiff asserts a claim for breach of the implied warranty of merchantability and fitness for a particular purpose against Rex. ECF No. 34, PageID.514–16. She alleges that Rex breached implied warranties because the Option Filter was not fit for its intended use and purpose. *Id.* at PageID.516.

Prevailing in a breach of implied warranty of fitness action requires a similar showing as a negligence action. *Prentis v. Yale Mfg.*, 365 N.W.2d 176, 186 (Mich. 1985) (holding that a negligence theory and warranty theory require the same showing, except that negligence focuses on the defendant's conduct and warranty focuses on the fitness of the product). In order to prevail, a plaintiff must therefore show: (1) the product was defectively manufactured; (2) the product reached the plaintiff in the same condition that it was in when it left the manufacturer; and (3) the defect proximately caused the plaintiff's injury. *See id.*; *see also Meemic Ins. Co. v. Hewlett-Packard Co.*, 717 F. Supp. 2d 752, 768 (E.D. Mich. 2010). In light of the Court's finding as to Plaintiff's negligence claim against Rex, the Court also concludes that Plaintiff has stated a plausible claim in order to proceed with her breach of implied warranty claim. *See Abdulkarim v. Medtronic, Inc.*, No. 17-cv-12898, 2017 WL 6342628, at *4 (E.D. Mich. Dec. 12, 2017) (finding that because both claims require the same analysis, the court's conclusions as to plaintiffs' negligence claim is appropriate for its conclusions as to plaintiffs' breach of implied warranty claim).

The Court takes notice of Rex's argument that it is entitled to a rebuttable presumption pursuant to Mich. Comp. Laws § 600.2946(4). ECF No. 37, PageID.559–61; *see also* ECF No. 42, PageID.755–56. Under this statute, a manufacturer of an implantable medical device is entitled to a presumption of no liability where the device was cleared by the FDA and subject to comprehensive FDA regulations applicable to its design and manufacture. The existence of a rebuttable presumption requires a plaintiff to offer admissible evidence to rebut the presumption. *Lesho v. Textron, Inc.*, 408 F. Supp. 2d 329, 334 (E.D. Mich. 2005). In its briefs, Rex cites to *Peter v. Stryker Orthopaedics, Inc.*, No. 07-13298, 2009 U.S. Dist. LEXIS 6322 (E.D. Mich. Jan. 29, 2009) in support of its argument that it's entitled to a rebuttable presumption at this juncture. Importantly, however, the *Peter* court analyzed the question of whether the rebuttable presumption applied after the parties engaged in discovery at the summary judgment stage of the proceedings. There, the court determined that the plaintiff failed to submit any evidence to rebut the presumption, and therefore granted summary judgment in defendant's favor. *Id.* at *8–9; *see also Lesho*, 408 F. Supp. 2d at 334 (determining that an expert witness' testimony was insufficient for plaintiff to rebut the presumption and defeat defendant's motion for summary judgment). Accordingly, the Court will deny Rex's Motion to the extent that it relies on the rebuttable presumption at this stage of the proceedings.

In sum, the Court will also deny Rex's Motion as it relates to Plaintiff's breach of implied warranty claim (Count II).

3. Breach of Express Warranty (Count III)

Plaintiff alleges in Count III that Rex breached express warranties under Michigan Uniform Commercial Code, Mich. Comp. Laws § 400.2313. ECF No. 34, PageID.517. She avers that Rex directed Argon to expressly represent and warrant that the Option Filter was safe and effective. *Id.* In its present Motion, Rex contends that, insofar as Plaintiff's breach of express warranty claim can be construed as one brought pursuant to the UCC, it should be dismissed because there was no contract between Plaintiff and Rex. ECF No. 37, PageID.556. Rex argues that "Plaintiff failed to establish privity of contract between herself and ... Rex. Where there is no contract, and therefore no bargain, there can be no express warranty under MCL § 400.2313." *Id.* (citation omitted).

Under Michigan law, "privity of contract is necessary for a remote purchaser to enforce a manufacturer's express warranty." *Montgomery v. Kraft Foods Global, Inc.*, 822 F.3d 304, 308 (6th Cir. 2016) (emphasis omitted) (quoting *Heritage Res., Inc. v. Caterpillar Fin. Servs. Corp.*, 774 N.W.2d 332, 343 n.12 (Mich. Ct. App. 2009)).⁶ To properly plead a breach of express warranty claim, then, Plaintiff needs

⁶ At the hearing, Plaintiff argued that there is no privity requirement since the Michigan Supreme Court has not decided this issue regarding express warranty claim. In *Montgomery*, the Sixth Circuit acknowledged that only a Michigan Court

to allege that she was in privity with Rex. *Id.* Upon review of Plaintiff's Third Amended Complaint, the Court agrees with Rex and finds that Plaintiff fails to allege the requisite contractual privity for her claim to survive. There is no allegation that the Plaintiff and Rex were parties to an agreement with one another. Plaintiff does not contend, for example, that she purchased the Option Filter directly from Rex. Rather, Plaintiff alleges that "through her medical providers" she purchased the Option Filter and that "through her attending physicians" she relied on the Defendants' purported representations. ECF No. 34, PageID.517–18. These allegations are insufficient to establish privity between Plaintiff and Rex specifically. Accordingly, to the extent that Plaintiff's breach of express warranty claim is based on the UCC, it will be dismissed. *See Tice v. Zimmer Holdings, Inc.*, No. 15-cv-134, 2015 WL 4392985, at *7 (W.D. Mich. July 15, 2015) (dismissing a breach of warranty claim where the plaintiffs failed to allege that they were parties to an agreement with defendants).

of Appeals has ruled on this question. 822 F.3d at 308. Nevertheless, the court explained that the Michigan Court of Appeals' decisions "are binding authority where the Michigan Supreme Court has never addressed the issue decided therein." *Id.* (citing *Berrington v. Wal-Mart Stores, Inc.*, 696 F.3d 604, 608 (6th Cir. 2012)) (internal quotation marks omitted). The court went on to rule that plaintiff "needed to allege that she was in privity with Defendants" in order to avoid dismissal of her breach of express warranty claim under the Michigan Uniform Commercial Code. *Id.* at 309.

Additionally, Rex argues that Plaintiff's Third Amended Complaint does not specify the terms of any alleged expressed warranty, nor does she include any factual support for allegations as to when, how, and by whom an express warranty was made. ECF No. 37, PageID.557. As explained above, a breach of express warranty claim under Michigan law requires: (1) proof of an express warranty, (2) reliance by the plaintiff; (3) the failure of the product to meet the warranty, and (4) damages caused by the failure. *See* M Civ JI 25.11. Similar to its claim as to Argon, Plaintiff does not specify the terms of an alleged express warranty. She instead avers generally that "[a]t the time and place of advertising, marketing, sale, distribution, and supply of the Option filter to Plaintiff," Rex specifically instructed Argon to make express warranties as to the Option Filter's safety, including that it was "prone to an unreasonably high incident of tilt, embedment, fracture, perforation of vessels and organs, and/or migration;" "prone to an unreasonably high incident of injury to the organs;" and that "[i]t was insufficient and strength or structural integrity". ECF No. 34, PageID.517–18. Plaintiff's express warranty claim as to Rex is devoid of any facts to when, how, and by whom an express warranty was made.

In sum, the Court will dismiss Plaintiff's breach of express warranty claim (Count III) against Rex.

4. Negligent Misrepresentation (Count IV)

In Count IV, Plaintiff brings forth a negligent misrepresentation claim against Rex. Plaintiff alleges that Rex instructed Argon to negligently provide her and her physicians with misrepresentations regarding the safety, efficacy, rate of failure, and approved uses of the Option Filter. ECF No. 34, PageID.519. In its Motion, Rex argues that it owed no duty to provide warnings to Plaintiff in light of the sophisticated user doctrine. ECF No. 37, PageID.566. Additionally, Rex asserts that Plaintiff's pleading fails to identify what, if any, misrepresentations were made by Rex and how she justifiably relied upon such misrepresentations to her detriment. *Id.*

To reiterate, a negligent misrepresentation claim under Michigan law includes the following elements: (1) defendant made a material representation; (2) the representation was false; (3) the defendant was negligent in making the misrepresentation, i.e. the defendant breached a professional duty of care to provide accurate information; and (4) the plaintiff suffered damages as a result. *Lackowski v. Twinlab Corp.*, No. 00-75058, 2001 U.S. Dist. LEXIS 25634, at *29–30 (E.D. Mich. Dec. 28, 2001). A plaintiff must also prove that she suffered damages as a result. *Id.*; *see also L. Offs. of Lawrence J. Stockler, P.C. v. Rose*, 436 N.W.2d 70, 81 (Mich. Ct. App. 1989).

While Rex does not rely on Federal Rule of Civil Procedure 9(b) in support of its argument to dismiss this claim, Plaintiff nevertheless focuses her Response on

the assertion that she “need not plead a negligent misrepresentation claim with particularly as required by Rule 9(b).” ECF No. 41, PageID.741 (citing *Santander Consumer USA, Inc. v. Superior Pontiac Buick GMC, Inc.*, No. 10-13181, 2011 U.S. Dist. LEXIS 33068, at *14–15 (E.D. Mich. Mar. 29, 2011)). As the Court explained above in relation to Argon’s Motion, however, this Court’s precedent establishes that a negligent misrepresentation claim must meet a heightened pleading standard set forth in Rule 9(b). *Miller v. Laidlaw & Co. (UK) Ltd.*, No. 11-12086, 2013 WL 1278484, at *1 (E.D. Mich. Mar. 27, 2013) (citing *Smith v. Bank of Am. Corp.*, 485 F. App’x 749, 752–53 (6th Cir. 2012); *Qadeer v. Bank of Am., N.A.*, 2013 WL 424776 (E.D. Mich. Feb. 4, 2013)). Plaintiff’s general allegations fail to put Rex on notice of any specific statements that were fraudulent, nor do they explain why such statements were fraudulent. Similar to its findings as to Argon, the Court denotes that Plaintiff also fails to indicate where and when any alleged misrepresentations were made. Accordingly, the Court concludes that Plaintiff fails to meet her burden under the heightened scrutiny pursuant to Rule 9(b). The Court will thus dismiss Plaintiff’s negligent misrepresentation claim (Count IV) as to Rex on these grounds.⁷

⁷ The Court takes notice of Rex’s argument related to the sophisticated user doctrine. ECF No. 37, PageID.567–68; ECF No. 42, PageID.759–60. According to Rex, it had no duty to provide device-related warnings information directly to Plaintiff, the end user, in light of Michigan’s sophisticated user doctrine. ECF No. 37, PageID.567. As indicated *supra*, the Court declines to rule in Rex’s favor based on this doctrine at this early stage of the proceedings. See *Tice v. Zimmer Holdings, Inc.*, No. 15-cv-134, 2015 WL 4392985, at *7 (W.D. Mich. July 15, 2015).

5. Plaintiff's Request for Additional Leave

As a final matter, as indicated *supra* in relation to Argon's Motion, the Court declines to afford Plaintiff another opportunity to amend at this juncture. In sum, to the extent that Rex seeks dismissal of Plaintiff's breach of express warranty (Count III) and negligent misrepresentation (Count IV) claims, its Motion will be granted. In all other respects, specifically as to Plaintiff's negligence (Count I) and breach of implied warranty (Count II) claims, its Motion will be denied.

V. CONCLUSION & ORDER

For the reasons articulated above, it is **HEREBY ORDERED** that Defendant Argon Medical Devices, Inc.'s Motion to Dismiss [#38] is **GRANTED**. It is therefore ordered that all claims against Defendant Argon Medical Devices, Inc. are dismissed with prejudice.

IT IS FURTHER ORDERED that Defendant Rex Medical, Inc., d/b/a Rex Medical, L.P., and Rex Medical, L.P.'s Motion to Dismiss [#37] is **GRANTED IN PART** and **DENIED IN PART**. It is therefore ordered that Counts III and IV against Defendant Rex Medical, Inc., d/b/a Rex Medical, L.P., and Rex Medical, L.P. are dismissed with prejudice.

IT IS FURTHER ORDERED that Plaintiff and Defendant Rex appear for a Scheduling Conference on May 5, 2021 at 10:00 a.m.

IT IS SO ORDERED.

Dated: April 12, 2021

/s/Gershwin A. Drain
GERSHWIN A. DRAIN
United States District Judge

CERTIFICATE OF SERVICE

Copies of this Order were served upon attorneys of record on
April 12, 2021, by electronic and/or ordinary mail.

/s/ Teresa McGovern
Case Manager